

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)				Attorney Docket Number: 8789-16CT		Serial No. to be assigned	
				Applicants: Hill et al.			
				Filing Date: concurrently herewith		Group to be assigned	
U. S. PATENT DOCUMENTS							
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
BB	1.	3,230,142	1/18/66	Spero	167	55	
	2.	3,487,152	12/30/69	Carstensen et al.	424	240	
	3.	3,502,772	3/24/70	Ijzerman	424	239	
	4.	3,568,828	3/9/71	Lerner	206	42	
	5.	3,591,688	7/6/71	Jones et al.	424	239	
	6.	3,639,600	2/1/72	Hendrix	424	242	
	7.	3,733,407	5/15/73	Segre	424	239	
	8.	3,795,734	3/5/74	Rocheft	424	238	
	9.	3,836,651	9/17/74	Rudel et al.	424	239	
	10.	3,813,418	05/28/74	Hofmeister et al.	260	397.4	
	11.	3,932,635	1/13/76	Segre	424	239	
	12.	3,939,264	2/17/76	Lachnit-Fixson	424	239	
	13.	3,942,641	3/9/76	Segre	206	534	
	14.	3,957,982	5/18/76	Lachnit-Fixson et al.	424	238	
	15.	3,969,502	7/13/76	Lachnit-Fixson	424	239	
	16.	4,027,019	5/31/77	Shroff	424	238	
	17.	4,066,757	1/3/78	Pasquale	424	243	
	18.	4,071,623	1/31/78	van der Vies	424	238	
	19.	4,145,416	3/20/79	Lachnit-Fixson et al.	424	238	
	20.	4,147,783	4/3/79	van der Vies	424	243	
	21.	4,154,820	5/15/79	Simoons	424	175	
	22.	4,210,644	7/1/80	Ewing et al.	424	239	
	23.	4,259,325	3/31/81	Prezewowsky et al.	424	238	
	24.	4,291,028	9/22/81	Vorys	424	238	
BB	25.	4,292,315	9/29/81	Vorys	424	240	

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B13	26.	4,315,925	2/16/82	Hussain et al.	424	239	
	27.	4,327,725	5/4/82	Cortese et al.	128	260	
	28.	4,378,356	3/29/83	De Jager	424	238	
	29.	4,383,993	5/17/83	Hussain et al.	424	239	
	30.	4,390,531	6/28/83	Edgren	424	239	
	31.	4,425,339	1/10/84	Pitchford	424	239	
	32.	4,512,986	4/23/85	Reel et al.	514	170	
	33.	4,530,839	7/23/85	Pasquale	514	171	
	34.	4,544,554	10/1/85	Pasquale	514	170	
	35.	4,616,006	10/7/86	Pasquale	514	170	
	36.	4,621,079	11/4/86	Lachnit-Fixson et al.	514	170	
	37.	4,628,051	12/9/86	Pasquale	514	170	
	38.	4,738,957	4/19/88	Laurent et al.	514	182	
	39.	4,756,907	7/12/88	Beck et al.	424	85	
	40.	4,762,717	8/9/88	Crowley, Jr.	424	425	
	41.	4,764,378	8/16/88	Keith et al.	424	435	
	42.	4,783,337	11/8/88	Wong et al.	424	468	
	43.	4,816,257	3/28/89	Buster et al.	424	430	
	44.	4,816,258	3/28/89	Nedberge et al.	424	448	
	45.	4,826,831	5/2/89	Plunkett et al.	514	170	
	46.	4,855,305	8/8/89	Cohen	514	171	
	47.	4,900,734	2/13/90	Maxson et al.	514	171	
	48.	4,914,089	4/3/90	Tax	514	170	
	49.	4,921,843	5/1/90	Pasquale	514	170	
	50.	4,962,098	10/9/90	Boissonneault	514	170	
B13	51.	4,977,147	12/11/90	Jungblut et al.	514	171	

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BB	52.	5,006,345	4/9/91	Lang	424	467		
	53.	5,010,070	4/23/91	Boissonneault	514	171		
	54.	5,043,331	8/27/91	Hirvonen et al.	514	170		
	55.	5,089,482	2/18/92	Hermens et al.	514	58		
	56.	5,098,714	3/24/92	Wright et al.	424	473		
	57.	5,108,995	4/28/92	Casper	514	170		
	58.	5,130,137	7/14/92	Crowley, Jr.	424	422		
	59.	5,183,814	2/2/93	Dukes	514	171		
	60.	5,200,197	4/6/93	Wright et al.	424	473		
	61.	5,208,225	5/4/93	Boissonneault et al.	514	178		
	62.	5,210,081	5/11/93	Raveendranath et al.	514	179		
	63.	5,262,408	11/16/93	Bergink	514	182		
	64.	5,276,022	1/4/94	Casper	514	170		
	65.	5,280,023	1/18/94	Ehrlich et al.	514	177		
	66.	5,288,717	2/22/94	Raveendranath et al.	514	179		
	67.	5,362,720	11/8/94	Labrie	514	169		
	68.	5,382,573	1/17/95	Casper	514	170		
	69.	5,418,228	5/23/95	Bennink	514	182		
	70.	5,434,146	7/18/95	Labrie et al.	514	169		
	71.	5,464,871	11/1995	Kun et al.	514	617		
	72.	5,510,342	4/23/96	Washburn et al.	514	179		
	73.	5,541,172	7/30/96	Labrie	514	169		
	74.	5,545,634	8/13/96	Labrie	514	169		
	75.	5,547,948	8/20/96	Barcomb	514	170		
	BB	76.	5,567,695	10/22/96	Labrie	514	169	
		77.	5,629,303	5/13/97	Labrie et al.	514	169	

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BB	78.	5,654,011	8/5/97	Jackson et al.	424	635
	79.	5,753,639	5/19/98	Labrie	514	169
	80.	5,759,576	6/2/98	Barcomb	424	479
	81.	5,759,577	6/2/98	Barcomb	424	479
	82.	5,807,586	9/15/98	Jackson et al.	424	630
	83.	5,846,960	12/8/98	Labrie	514	169
	84.	5,861,387	1/19/99	Labrie et al.	514	169
	85.	5,861,431	1/19/99	Hildebrand et al.	514	557
	86.	5,908,638	6/1/99	Huber et al.	424	465
	87.	5,998,639	12/7/99	Raijmakers, et al.	552	625
BB	88.	Re. 36,247	7/6/99	Plunkett et al.	514	170
	89.	6,040,333	3/21/00	Jackson	514	456

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T	Document Number	Date	Country	Class	Subclass	Translation Yes No	
BB	90.	IL25265	12/31/69	Israel	—	—	
	91.	1214712	12/2/70	Great Britain	—	—	
BB	92.	DT2431694 A1	3/4/76	Germany	—	—	
	93.	DT2624025 A1	12/9/76	Germany	—	—	
BB	94.	1561244	2/13/80	Great Britain	—	—	
	95.	GB2096462A	10/20/82	Great Britain	—	—	
BB	96.	DE3341638 A1	11/17/83	Germany	—	—	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
BB	97.	Andreolini, et al., <i>Estrogen Conjugates in Late-Pregnancy Fluids: Extraction and Group Separation by a Graphitized Carbon Black Cartridge and Quantification by High-Performance Liquid Chromatography</i> , Anal. Chem. 59:1720-1725 (1987).	
BB	98.	Fujino, et al., <i>3-(Difluoro-1,3,5-trianinyl)-1-(ethylthio)-2-n-propylbenz[<i>f</i>]isoindole as a Fluorescence Derivation Reagent for Estrogens in High-Performance Liquid Chromatography</i> , Chem. Pharm. Bull., 37(7): 1939-1940 (1989).	
	99. ✓	Vest, Floyd B. & Karnes, H. Thomas, <i>Luminescent Derivation of Estrogens for HPLC Detection</i> (Abstract), Department of Pharmacy and Pharmaceutics, Medical College of Virginia, APQ 1198. <i>not needed</i>	
BB	100.	Takadate, et al., <i>A Convenient Derivatization with Anion Exchange Resin Catalysis for High-Performance Liquid Chromatographic Analysis. I. Derivatization of Estrogens with Dansyl Chloride</i> , Chem. Pharm. Bull., 33(11): 5092-5095 (1985).	
	101.	Novakovic, et al., <i>High-Performance Liquid Chromatographic Determination of Equine Estrogens with Ultraviolet Absorbance and Electrochemical Detection</i> , Journal of Chromatography A, 678: 359-363 (1994).	
	102.	Townsend, et al., <i>High-Performance Liquid Chromatographic Determination of Conjugated Estrogens in Tablets</i> , Journal of Chromatography, 450: 414-419 (1988).	
	103.	Ishida, et al., <i>Determination of Oestrogens in Pregnancy Urine by High-Performance Liquid Chromatography with Fluorescence Detection</i> , Journal of Chromatography, 431: 249-257 (1988).	
	104.	<i>Conjugated Estrogens</i> , The United States Pharmacopoeia (USP), published by United States Pharmacopeial Convention, Inc., pp. 627-629 (2000).	
	105.	Synthetic Generic Conjugated Estrogens: Timeline, May 5, 1997, http://www.fda.gov/cder/news/cetimeline.htm .	
	106.	FDA Statement on Generic Premarin, HHS News Press Release, P97-12, May 5, 1997, http://www.fda.gov/cder/cepressrelease.htm .	
	107.	New Drug Approval for Cenestin, Synthetic Conjugated Estrogens, A: March 24, 1999, <i>Questions and Answers</i> , http://www.fda.gov/cder/news/cenestin/qa.htm .	
	108.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Physicians Package Insert, pp. 1 - 10 (1999).	
	109.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Patient Package Insert, pp. 11 - 13 (1999).	
	110.	FDA Backgrounder on Conjugated Estrogens, May 5, 1997, http://www.fda.gov/cder/cebackground.htm .	
BB	111.	Letter from Yana Ruth Mille, Chief, Compndial Operations Staff, HFD-354, Office of Pharmaceutical Science, Center for Drug Evaluation & Research to Joseph G. Valentino, J.D., Senior Vice President and General Counsel, The United States Pharmacopeial Convention, Inc. (March 8, 2000) (REF: 3-00-001-O).	

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BB	112.	Letter from Yana Ruth Mille, Chief, Compendial Operations Staff, HFD-354, Office of Pharmaceutical Science, Center for Drug Evaluation & Research to Joseph G. Valentino, J.D., Senior Vice President and General Counsel, The United States Pharmacopeial Convention, Inc. (March 8, 2000) (REF: 3-00-002-O).	
	113.	Memorandum from Janet Woodcock, M.D., Director, Center for Drug Evaluation & Research to Douglas L. Sporn, Director, Office of Generic Drugs, regarding Approvability of a Synthetic Generic Version of Premarin (May 5, 1997).	
	114.	Sakac, Marijan N. et al., "Chemical Behavior of 3, 17.beta.-dipropionoxy-9.alpha.-hydroxyestra-1,3,5(10)-trien-6-one," <i>DATABASE CHEMABS 'ONLINE'</i> , Database accession no. 128:180573 XP002171996, J. Serb. Chem. Soc., 63(1): 21-24 (1998).	
	115.	Wiese, Thomas et al., "Induction of the Estrogen Specific Mitogenic Response of MCF-7 Cells by Selected Analogues of Estradiol-17 β : A 3D Study," <i>Journal of Medicinal Chemistry</i> , 40(22): 3659-3669 (1997).	
	116.	Yang et al., "The Hydroxylation and Amidation of Equilenin Acetate Catalyzed by Chloro[5,10,15,20-tetrakis(pentafluorophenyl)porphyrinato]manganese(III)," <i>Chem. Commun.</i> , 7: 531-532 (2000).	
BB	117.	Yang, Jerry et al., "Regioselective Oxidations of Equilenin Derivatives Catalyzed by a Rhodium(III) Porphyrin Complex-Contrast with the Manganese(III) Porphyrin," <i>Tetrahedron Letters</i> , 41(42): 8063-8067 (2000).	
	118.	International Search Report corresponding to PCT/US 01/07544; mailed on August 6, 2001 <i>ref. needed</i>	
BB	119.	Rzheznikov, V. M. et al., "Synthesis and Biological Activity of Estrone 8-iso- and D-homoanalogs Oxidized for Rings B and C," <i>DATABASE CHEMABS 'Online'</i> , Database accession no. 110:108353 XP002171997, Khim.-Farm. Zh. 22(12): 1462-1465 (1988).	
	120.	Sakac, Marija N. et al., "Synthesis of New Steroidal N-butyl-N-methyl-undecanamide Derivatives," <i>DATABASE CHEMABS 'Online'</i> , Database accession no. 133:335378 XP002171995, ZB. MATICE SRP. PRIR. NAUKE 96: 5-9 (1999)	
	121.	Center for Drug Evaluation and Research (CDER), Guidance for Industry, Draft Guidance, <i>Conjugated Estrogens, USP - LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence</i> , March 2000, < http://www.fda.gov/cder/guidance/index.htm >.	
BB	122.	Physician's Desk Reference, 53: 3367-3379 (1999).	

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